"Contains NO CBI"

UNION CARBIDE

UNION CARBIDE CORPORATION 39 OLD RIDGEBURY ROAD, DANBURY, CT 06817-0001

8EHQ-92-12108
8892000103 46
INIT

August 27, 1992

A

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Room L-100
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

92 SEP -1 AM 11:39

Attn: Section 8(e) Coordinator (CAP Agreement)

Re: CAP Agreement Identification No. 8ECAP-0110

Dear Sir or Madam:

Union Carbide Corporation ("Union Carbide") herewith submits the following report pursuant to the terms of the TSCA §8(e) Compliance Audit Program and Union Carbide's CAP Agreement dated August 14, 1991 (8ECAP-0110). This report (comprising several documents, described below) describes the sensitizing potential of Silane A-187, Silane X-87, Silane A-1100, and Silane Z-38. The compositional identification of these products follows:

Silane A-187: Silane, trimethoxy[3-(oxiranylmethoxy)propyl-] (CASRN 2530-83-8).

Silane X-87: (~55%) 2-Propenoic acid, ethyl ester, polymer with 1,2-ethanediamine and trimethoxy [2-(7-oxabicyclo][4.1.0]hept-3-yl)ethyl]silane (CASRN 67674-62-8), and (~45%) methanol (CASRN 67-56-1).

Silane A-1100: 3-Aminopropyltriethoxysilane (CASRN 919-30-2).

Silane Z-38: (~50%) 1,2-Ethanediamine, N-(Phenylmethyl)-N'-[3-(trimethoxy-silyl)propyl]-, monohydrochloride (CASRN 42965-91-3), and (~50%) methanol (CASRN 67-56-1).

silane

hm
2/15/95

UCC letter from M. R. Huffman to D. L. Voisinet, July 29, 1980 (with attachments); and UCC letter from J. G. Marsden to J. F. Tancredi, (File No. M-78-268), May 22, 1978 (with attached conclusions (in French) from Prof. P. E. Fournier [12/7/77; 5/23/77; 1/14/77; 1/28/77]).

A complete summary of this report is attached.

Previous TSCA Section 8(e) or "FYI" Submission(s) related to this substance are:

(None)

Previous PMN submissions related to this substance are: (None)

This information is submitted in light of EPA's current guidance. Union Carbide does not necessarily agree that this information reasonably supports the conclusion that the subject chemical presents a substantial risk of injury to health or the environment.

In the attached report the term "CONFIDENTIAL" may appear. This precautionary statement was for internal use at the time of issuance of the report. Confidentiality is hereby waived for purposes of the needs of the Agency in assessing health and safety information. The Agency is advised, however, that the publication rights to the contained information are the property of Union Carbide.

Yours truly,

William C. Kuryla, Ph.D.
Associate Director
Product Safety
(203/794-5230)

WCK/cr
Attachment (3 copies of cover letter, summary, and report)

silane

SUMMARY

Chemicals and Plastics
Research and Development Department
Tarrytown, New York

MEMORANDUM

RECEIVED
MAY 16 1980
B. Ballantyne, M. D.

TO: J. F. Tancredi

FROM: J. G. Marsden

DATE: May 22, 1978

FILE NO.: M-78-268

SUBJECT: Toxicity - A-1100, A-187, X-87, and Z-38

St. Gobain routinely has toxicity testing carried out on silane coupling agents that are or may be used in commercial sizing of glass fibers. Due to the nature of their operation and past history, they are particularly concerned with skin irritation. They feel the Magnusson test correlates with their plant experiences and they rely heavily on it.

As a result of my request that they share some of their test results with us, I received copies, in French, of the results they have on A-1100, A-187, X-87, and Z-38.

A brief summary of their results are:

A-1100	low order of toxicity
Z-38	intermediate level of toxicity, likely would not generate worker problems
A-187	high response level. Would not cause panic removal from commercial size; but would be excluded from new developments.
X-87	extreme response level. 100% of test animals positive. Would not be continued in commercial products.

UNION CARBIDE

INTERNAL CORRESPONDENCE

Report

A8

A-187 Y-9138?
Y-5987 Positive

HEMICALS AND PLASTICS

P. O. BOX 8361, SOUTH CHARLESTON, WEST VIRGINIA 25303

AFDR

(Name) Mr. D. L. Voisinet

vision

cation SISTERSVILLE

py to Bryan Ballantyne, M.D. - 511
Dr. W. C. Kuryla - 511
Mr. D. Liebeskind - Danbury
Mr. W. E. Whitehurst - 511

Date July 29, 1980

Originating Dept. Research & Development

Subject Material Safety Data Sheets, Silanes

Don:

Recently, you called attention to some French studies which identify Silanes A-187, X-87 and Z-38 as potential sensitizers to humans.

As a result of this new information, Dr. Ballantyne has requested that the Material Safety Data Sheets (MSDS) for these products be revised. The appropriate comments for Sections III and V of the MSDS are attached.

Please feel free to call if there are questions.

Very truly yours,

M. R. Huffman
Health Information Manager

MRH/slh

Attachment

Silane X-87

Results

% Sensitization	Grade	Sensitization Potential
100%	V	Extreme

Conclusions

The Magnusson test used in our laboratories on 10 Hartley guinea pigs produced Grade V allergic response, which correspond to an EXTREME potential for sensitization.

X-87 must be considered a product presenting an allergenic risk to man.

RECEIVED
MAY 30 1980
B. Ballantyne, M. D.

Unite de Pharmacology Clinique

Conclusion

The Magnusson test, carried out in our laboratories on 10 Hartley guinea pigs in the presence of Silane A 187, indicates a IV degree of allergenicity, corresponding to a STRONG sensitivity character.

As to the seriousness of the lesions, we observed 48 h after the discontinuation of the reaction a medium diffuse redness at 5 guinea pigs and weak dispersed redness at 3 guinea pigs. 80% sensitized (8/10) high concern

72 h after the discontinuation of the reaction, 4 guinea pigs showed intense redness with eczematization of the initial lesions. These lesions disappeared 10 days after the discontinuation of the reaction.

The risk to see allergic accidents appear in men in the course of prolongued exposure to SILANE A 187 must be checked.

Page 2:

Conclusion: The Magnusson test, carried out in our laboratories on 10 Hartley guinea pigs indicates a V degree of allergenicity and an EXTREME character. 10/10 (100%) sensitized high concern

X-87 should be considred as a product, causing a risk of unexpected allergic phenomena in men.

Page 3:-

Conclusion: The Magnusson test, carried out in our laboratories on 10 Hartley guinea pigs indicates a I. degree of allergenicity and a LOW character.

SILANE A 1100 can be considered as a product, displaying a low allergizing nature and it is little probable, that it would have allergic effect in men.

Sensitization of 1/10
low concern

Page 4:-

Conclusion: The Magnusson test, carried out in our laboratories on HARTley gunea pigs with hydrolyzed SILANE Z-38 indicates an allergenicity degree of III. and a MEDIUM character. 4/10 (40%) sensitized medium concern

Hydrolyzed SILANE Z-38 should be considered as a product displaying a medium allergy causing character, that is, a character, which is probably not sensibilyzing for men.

Chemicals and Plastics
Research and Development Department
Tarrytown, New York

MEMORANDUM

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MAY 16 1980

TO: J. F. Tancredi

B. Ballantyne, M. D.

FROM: J. G. Marsden

DATE: May 22, 1978

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A-187	high response level. Would not cause panic removal from commercial size; but would be excluded from new developments.
X-87	extreme response level. 100% of test animals positive. Would not be continued in commercial products.

For your convenience I have attached Mellon data on X-871 and Z-38 as well as some interpretation by our medical group. Obviously the Magnusson test is more sensitive than the range finding tests we currently use.

J. G. Marsden/lad
Attachments

J G Marsden

cc: B. Prokai

200, rue du Faubourg Saint-Denis 75010 PARIS
203.14.71 (postes 420 - 421 - 422) - 202.95.20

PROFESSEUR P. E. FOURNIER
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PROFESSEUR R. BOURDON
Directeur de la Chimie Analytique
PROFESSEUR Agrégé M. L. EFTHYMIOU
Directeur des Études Cliniques
DOCTEUR E. ROSENBERG
Directeur Technique et Coordination
DOCTEUR J. CROUZETTE
Département Clinique

CONCLUSION

Le test de Magnusson effectué dans nos Laboratoires sur 10 cobayes Hartley, en présence du SILANE A 187, met en évidence un degré d'allergénicité à IV correspondant à un caractère de sensibilisation FORT.

En ce qui concerne la gravité des lésions, nous avons noté 48 heures après le déclenchement de la réaction une rougeur moyenne diffuse chez 5 cobayes et une rougeur faible dispersée chez 3 cobayes.

72 heures après déclenchement de la réaction, 4 cobayes ont montré des rougeurs intenses avec eczématisation des lésions initiales. Ces lésions ont disparu 10 jours après le déclenchement de la réaction.
Le risque de voir apparaître des accidents allergiques chez l'homme au cours d'une exposition prolongée au SILANE A 187, doit être retenu.

Fait à PARIS, le 7 Décembre 1977

PROFESSEUR P.E. FOURNIER.

HOPITAL FERNAND WIDAL
200, rue du Faubourg Saint-Denis - 75010 PARIS
Tél. 202.95.20 (ligne directe)
Tél. 203.14.71 (poste 429)

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Directeur Scientifique

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Directeur des Etudes Cliniques

DOCTEUR E. ROSENBERG
Directeur Technique et Coordination

RESULTAT

% de sensibilisation	degré	caractère
100 %	V	EXTREME

CONCLUSION

Le test de Magnusson effectué dans nos laboratoires sur 10 cobayes Hartley met en évidence un degré d'allerginicité à V et un caractère EXTREME.

Le X-87 doit être considéré comme un produit présentant un risque de survenue de phénomènes allergiques chez l'homme.

Fait à PARIS, le 23 Mai 1977

PROFESSEUR P.E. FOURNIER.

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MADAME C. BOURGEOIS
MADAME A. LECORSIER
Département Biochimie

DOCTEUR J. CROUZETTE
DOCTEUR Y. PARLIER
Département Clinique

RESULTAT

% de sensibilisation	degré	caractère
10 %	I	Bas

CONCLUSION

Le test de Magnusson effectué dans nos laboratoires sur 10 cobayes Hartley met en évidence un degré d'allergénicité à I et un caractère BAS.
Le silane A 1100 peut être considéré comme un produit présentant un caractère allergisant bas et il est peu probable qu'il provoque un effet allergisant chez l'homme.

Fait à PARIS, le 14 Janvier 197

PROFESSEUR P.E. FOURNIER.

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PROFESSEUR Agrégé M.L. EFTHYMIOU
Directeur des Etudes Cliniques

DOCTEUR E. ROSENBERG
Directeur Technique et Coordination

RESULTAT

% de sensibilisation	degré	caractère
40 %	III	MOYEN

CONCLUSION

Le test de Magnusson effectué dans nos laboratoires sur des cobayes Hartley avec le SILANE Z-38 hydrolysé met en évidence un degré d'allergénicité à III et un caractère MOYEN.

Le SILANE Z-38 hydrolysé doit être considéré comme un produit présentant un caractère allergisant moyen, donc un caractère probablement pas sensibilisant chez l'homme.

Fait à PARIS, le 28 JANVIER 1977

PROFESSEUR P.E. FOURNIER.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

William C. Kuryla, Ph.D.
Associate Director, Product Safety
Union Carbide Corporation
39 Old Ridgebury Road
Danbury Connecticut 06817-0001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and **refer to the reverse side of this page for "EPA Information Requests"**.

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12108A

Recycled/Recyclable
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Triage of 8(e) Submissions

Date sent to triage: APR 20 1995

NON-CAP CAP

Submission number: 12108A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

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entire document: 0 1 2 **pages** 1,2, **pages** 1,2,3,TAB

Notes:

Contractor reviewer : PJR **Date:** 4/3/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 0992 - 12108 SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Union Carbide Corporation

SUB. DATE: 08/27/92 OTS DATE: 09/01/92 CSRAD DATE: 02/15/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:
Silane A-187
Silane A-1100

CAS#
2530-83-8
67674-62-8
67-56-1
919-30-2
42965-91-3
Silane X-87 → none
Silane Z-38 → none

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	0248	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA:

NON-CBI INVENTORY: YES / NO

ONGOING REVIEW: YES (DROP/REFER) / NO (CONTINUE)

SPECIES: CP

TOXICOLOGICAL CONCERN: LOW / MED / HIGH

USE:

PRODUCTION:

CAS SR

DETERMINI

REFER

COMMENTS

8(E)-12108A

H/H/L/M

SILANE A 187: DERMAL SENSITIZATION IN HARTLEY GUINEA PIGS IS OF HIGH CONCERN BASED ON STRONG SENSITIZATION POTENTIAL WITH AN 80% (8/10) SENSITIZATION RATE IN THE MAGNUSSON TEST. FORTY-EIGHT HOURS AFTER THE DISCONTINUATION OF THE REACTION A MEDIUM DIFFUSE REDNESS IN 5 GUINEA PIGS AND WEAK DISPERSED REDNESS IN 3 GUINEA PIGS WAS OBSERVED. 72 HOURS AFTER DISCONTINUATION OF THE REACTION, 4 GUINEA PIGS SHOWED INTENSE REDNESS WITH ECZEMATION OF THE INITIAL LESIONS. LESIONS DISAPPEARED 10 DAYS AFTER INITIAL APPLICATION.

SILANE X-87: DERMAL SENSITIZATION IN HARTLEY GUINEA PIGS IS OF HIGH CONCERN BASED ON AN EXTREME SENSITIZATION POTENTIAL WITH A 100% (10/10) SENSITIZATION RATE IN THE MAGNUSSON TEST.

SILANE A 1100: DERMAL SENSITIZATION IN HARTLEY GUINEA PIGS IS OF LOW CONCERN BASED ON A 10% (1/10) SENSITIZATION RATE IN THE MAGNUSSON TEST.

SILANE Z-38: DERMAL SENSITIZATION IN HARTLEY GUINEA PIGS IS OF MEDIUM CONCERN BASED ON A 40% (4/10) SENSITIZATION RATE IN THE MAGNUSSON TEST.